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IN THE

# Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.
*Petitioner/Cross-Respondent,*
v.
LORA LOHR AND MICHAEL LOHR,
*Respondents/Cross-Petitioners.*

**On Writs of Certiorari to the United States Court of Appeals for the Eleventh Circuit**

## BRIEF OF THE HEALTH INDUSTRY MANUFACTURERS ASSOCIATION AND MEDMARC INSURANCE COMPANY AS *AMICI CURIAE* IN SUPPORT OF PETITIONER/CROSS-RESPONDENT, MEDTRONIC, INC.

Of Counsel:

DONNELLDA RICE
General Counsel
Health Industry
Manufacturers Association
1200 G Street, N.W.
Washington, D.C. 20005
(202) 783-8700

BRUCE N. KUHLIK
*Counsel of Record*
JENNIFER A. JOHNSON
Covington & Burling
1201 Pennsylvania Ave., N.W.
Washington, D.C. 20044
(202) 662-6000
*Counsel for Health Industry Manufacturers Association*

PAUL J. MALONEY
WILLIAM J. CARTER
SAMUEL J. SMITH, JR.
Carr, Goodson, Lee & Warner
1301 K Street, N.W.
Washington, D.C. 20005-3300
(202) 310-5500
*Counsel for MEDMARC Insurance Company, Inc.*

March 13, 1996

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## QUESTION PRESENTED

Whether the Food and Drug Administration's comprehensive regulation of medical devices establishes requirements that preempt state-law product liability and related claims pursuant to section 521 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k.

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## INTEREST OF THE *AMICI CURIAE*

The Health Industry Manufacturers Association (HIMA) is the principal trade association of the medical technology industry. Founded in 1974, HIMA represents more than 700 manufacturers of medical devices, diagnostic products, and health information systems, along with component manufacturers and manufacturing services suppliers. HIMA's members manufacture more than 90 percent of the nearly $40 billion of health care technology products purchased annually in the United States.

MEDMARC Insurance Company, Inc. (MEDMARC) is a specialty insurer which provides product liability coverage for medical device manufacturers. Owned and controlled by its members, MEDMARC was founded in 1979 in response to volatile conditions in the commercial insurance market for product liability insurance. MEDMARC's membership includes approximately 550 manufacturers and distributors of medical devices and diagnostic products.

The present case raises an issue of fundamental and overriding importance to the medical device industry. *Amici* are concerned that the imposition of inconsistent state requirements on medical device manufacturers through product liability awards will stifle innovation and interfere with the availability of life-saving technologies.[1/]

## SUMMARY OF ARGUMENT

Congress preempted additional or inconsistent state requirements to protect a uniform national market for medical devices. In enacting the express preemption provision of the Medical Device Amendments, Congress carefully weighed the need for innovation and progress in the medical device field, which is fostered by a uniform national regulatory system,

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[1/] Pursuant to Rule 37 of the Rules of this Court, the parties have consented to the filing of this brief. Their letters of consent have been filed with the Clerk of the Court.

against the interests of the states in imposing their own inconsistent or additional requirements. Congress struck the balance by placing the regulation of the safety and effectiveness of medical devices solely in the hands of the Food and Drug Administration (FDA), thus ensuring that no single state can raise its individual interests above the congressional policy favoring development and regulation of medical devices under a single national authority.

Pursuant to its statutory mandate, the FDA has established a comprehensive system to assure the safety and effectiveness of medical devices. The FDA utilizes a variety of regulatory controls to ensure that device manufacturers are subject to appropriate safety and effectiveness requirements for their products. Among other things, the FDA conducts premarket review and approval of product submissions, imposes specific manufacturing and labeling requirements, and implements a classification scheme and product review policy to ensure that medical devices receive the appropriate level of safety and effectiveness review. As Congress expressly decreed, these and other requirements imposed on medical device manufacturers under the FDA's complex regulatory framework preempt different or additional state requirements, including those imposed through product liability and related claims.

Congress recognized that state product liability exposure relating to the safety or effectiveness of medical devices would threaten innovation and impede the availability of important medical technologies. Indeed, liability concerns already have driven valuable products off the market and have hindered critical research deemed to present too high a liability risk. To prevent these detrimental influences from chilling the advancement of medical device technology, Congress entrusted the safety and effectiveness of devices exclusively to the FDA's expert authority.



## ARGUMENT

### I. THE FDA'S COMPREHENSIVE REGULATION OF DEVICES ESTABLISHES REQUIREMENTS THAT EXPRESSLY PREEMPT STATE PRODUCT LIABILITY AND RELATED CLAIMS.

In 1976, Congress enacted the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FD&C Act). The new legislation greatly enhanced the FDA's authority to ensure that medical devices are safe and effective for their intended uses. To ensure that the FDA's expert regulatory control would not be undermined by divergent state requirements, Congress included an express preemption provision in the legislation, providing that a state requirement is preempted if it is "different from, or in addition to" any applicable federal requirement relating to device safety or effectiveness.[2/] Pursuant to its congressional mandate, the FDA has developed a complex regulatory framework for assuring the safety and effectiveness of medical devices. An award of damages to a plaintiff under state law would impose requirements for medical devices that are different from or in addition to those imposed under the FDA's comprehensive regulatory scheme. Therefore, claims against medical device manufacturers premised on state product liability, warranty, or similar laws (whether imposed by statute or by common law) are expressly preempted.

#### A. Congress And The FDA Have Established A Comprehensive Scheme For Regulating The Safety And Effectiveness Of Medical Devices.

Under the MDA, the FDA comprehensively regulates the safety and effectiveness of medical devices. Through this system, the FDA implements a variety of regulatory controls,

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2/ FD&C Act § 521(a), 21 U.S.C. § 360k(a).

which operate in concert to facilitate the availability of important medical devices while ensuring that products posing unreasonable risks to public health and safety are not released into or are removed from the market. With the assistance of expert advisory panels, the FDA exercises its statutory discretion to tailor the level of regulatory control and review for specific medical devices to fit the particular safety and effectiveness concerns they raise. Through the classification scheme, premarket approval process, "510(k)" premarket notification and authorization process, performance standards, and general controls, the FDA assures the safety and effectiveness of medical devices.

1. **The FDA implements a classification scheme to ensure that medical devices receive the appropriate level of safety and effectiveness review.**

As required by Congress, the FDA imposes requirements based on the level of regulation the agency deems necessary to assure the safety and effectiveness of particular devices. The FDA implements a statutory classification scheme to determine the level of scrutiny appropriate for different types of medical devices.[3/] Devices are classified in one of three categories — Class I, Class II, or Class III. Devices classified in Class I are deemed to pose the lowest risk to human health and are subject to general controls under the FD&C Act.[4/] In addition, unless exempted by the FDA, Class I devices can be marketed only through the section 510(k) premarket notification and authorization process, described below.

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[3/] *See* FD&C Act §§ 513, 514(b), 515(b), and 520(l), 21 U.S.C. §§ 360c, 360d(b), 360e(b), and 360j(l); 21 C.F.R. Part 860.

[4/] 21 C.F.R. § 860.3(c)(1); FD&C Act § 513(a)(1)(A), 21 U.S.C. § 360c(a)(1)(A). General controls are discussed below in part I.A.5.



The FDA places a medical device in Class II if it determines that the device requires additional regulatory controls to assure its safety and effectiveness.[5/] Class II devices are subject to general controls and the section 510(k) requirements. In addition, they may be subject to "special controls," such as particularized performance standards, postmarket surveillance, patient registries, and other appropriate actions the FDA deems necessary to assure safety and effectiveness.[6/] For example, the FDA imposes specific labeling requirements on manufacturers of tampons regarding the risk of toxic shock syndrome to assure that these devices are used in a safe and effective manner.

The FDA will classify a medical device in Class III if the device is "life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury."[7/] A Class III device cannot be marketed except pursuant to an affirmative grant of authority by the FDA, which imposes precise conditions governing the device's design, manufacture and labeling. The manufacturer of a Class III medical device may obtain the required marketing authority from the FDA via one of two premarket review processes — the section 515 premarket approval process or, for devices "substantially equivalent" to pre-MDA devices and not required to go through the section 515 procedure, the section 510(k) premarket notification and authorization process.

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[5/] 21 C.F.R. § 860.3(c)(2); FD&C Act § 513(a)(1)(B), 21 U.S.C. § 360c(a)(1)(B).

[6/] 21 C.F.R. § 860.3(c)(2).

[7/] 21 C.F.R. § 860.3(c)(3); FD&C Act § 513(a)(1)(C), 21 U.S.C. § 360c(a)(1)(C).

**2. The FDA authorizes the marketing of most medical devices through the section 510(k) premarket notification and authorization process.**

Like the pacemaker lead at issue in the instant case, most medical devices are marketed through the premarket notification process under section 510(k) of the FD&C Act.[8/] A medical device may be marketed pursuant to a premarket notification, or "510(k)", if the device is "substantially equivalent" to a predicate device (*i.e.*, a device marketed before enactment of the MDA on May 28, 1976), and if the FDA has not specifically required a premarket approval application (PMA) for the device. Before granting marketing authority, the FDA must determine that the device is substantially equivalent in safety and effectiveness to the predicate device. The FDA's implementation of the section 510(k) process is discussed in more detail in section I.B. below.

**3. The FDA requires certain Class III devices to obtain marketing authority through the premarket approval process.**

A significant number of Class III devices are marketed pursuant to the PMA process. A PMA is required to market a Class III medical device if the device is not substantially equivalent to a pre-amendment device or if the FDA specifically requires a PMA for that device. The PMA process subjects Class III devices to comprehensive FDA requirements regulating all aspects of their design, labeling, and manufacture.[9/]

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[8/] 21 U.S.C. § 360(k).

[9/] Through the Investigational Device Exemption (IDE) regulations, the FDA also subjects investigational devices involved in clinical trials to a (continued...)



In preparing a PMA, a medical device manufacturer must conduct an exhaustive review and analysis of the device's safety and effectiveness. Among other things, the PMA must include "full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective" and "a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device."[10/] The PMA also must include "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device."[11/] Moreover, a GMP inspection of the applicant's manufacturing facilities is conducted by the FDA before the PMA will be approved.[12/]

Because this case involves a device marketed through the section 510(k) process, we will not further discuss the PMA process. The preemptive effect of requirements imposed under the PMA process follows *a fortiori* from the preemptive effect of section 510(k) requirements. In any event, the factors that led the court below to stop short of full preemption have no application to the PMA context.

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[9/](...continued)
high level of regulatory oversight and control. *See* FD&C Act § 520(g), 21 U.S.C. § 360j(g); 21 C.F.R. Part 812.

[10/] FD&C Act §§ 515(c)(1)(A), 515(c)(1)(B), 21 U.S.C. §§ 360e(c)(1)(A), 360e(c)(1)(B).

[11/] FD&C Act § 515(c)(1)(C), 21 U.S.C. § 360e(c)(1)(C).

[12/] FDA Compliance Program Guidance Manual, Program 7383.001, Medical Device Premarket Approval and Postmarket Inspections (March 1994).

**4. The FDA may take regulatory action if new safety or effectiveness concerns are raised.**

Even after the FDA grants marketing authority for a Class III device through the section 510(k) or PMA process, device manufacturers are subject to comprehensive recordkeeping and reporting obligations to ensure that they obtain and report to the FDA the most up-to-date information bearing on safety and effectiveness.[13] The FDA has broad authority to withdraw approval of a PMA and to take enforcement action against devices marketed under section 510(k).[14] In addition, the agency often directs manufacturers to add or modify warnings in light of new information.[15]

**5. The FD&C Act and FDA regulations impose safety and effectiveness requirements on all medical devices.**

All medical devices are subject to certain "general controls" under the FD&C Act and FDA regulations. Among other things, these general controls include good manufacturing practice (GMP) and warning requirements.

**a. *GMP regulations***

The GMP regulations (21 C.F.R. Part 820) impose comprehensive requirements on manufacturers of medical devices, covering "methods used in, and the facilities and

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[13] *See* FD&C Act §§ 510, 519, 21 U.S.C. §§ 360, 360i; 21 C.F.R. §§ 803.24, 803.31, 807.20-807.31.

[14] *See, e.g.*, FD&C Act §§ 302 (injunction proceedings), 303 (penalties), 304 (seizure), 513(e) (classification changes), 515(e) (withdrawal and temporary suspension of approval of application), 518 (notification and other remedies), 21 U.S.C. §§ 332, 333, 334, 360c(e), 360e(e), 360h.

[15] *See* FD&C Act §§ 502(a), 502(f)(2), 502(j), 21 U.S.C. §§ 352(a), 352(f)(2), 352(j).



controls used for, the manufacture, packing, storage, and installation of all finished devices intended for human use."[16] These regulations are "intended to assure that such devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act."[17]

Under the GMP regulations, medical device manufacturers must prepare and implement a quality assurance program "that is appropriate to the specific device manufactured" and in accordance with the GMP requirements.[18] The GMP regulations impose extensive quality, manufacturing, design, label control, and recordkeeping requirements on all medical devices,[19] with particularized provisions applicable to critical devices (*i.e.*, devices that are intended for surgical implant or to support or sustain life and whose failure to perform will likely result in significant injury).[20] Any failure of a device or any of its components to meet specifications after it has been released into the market must be investigated by the manufacturer, and the investigation, along with any conclusions or follow-up, must be documented.[21]

**b. *Warning requirements***

There are several statutory provisions bearing on device labeling. These provisions include section 502(f)(2) of the

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[16] 21 C.F.R. § 820.1.

[17] *Id.*

[18] 21 C.F.R. § 820.5.

[19] 21 C.F.R. Part 820.

[20] *See* 21 C.F.R. §§ 820.3(e), 820.3(f), 820.81, 820.101, 820.116, 820.121, 820.151, 820.161, 820.182, 820.185, 820.195.

[21] 21 C.F.R. § 820.162.

FD&C Act,[22] which requires "adequate warnings," section 502(a),[23] which prohibits false or misleading labeling, and section 201(n),[24] which, together with section 502(a), prohibits misleading omissions.

In addition, section 502(f)(1) requires device labeling to bear "adequate directions for use."[25] Prescription medical devices, such as the pacemaker lead at issue in the present case, are exempt from the provision requiring "adequate directions for use," if they comply with the labeling requirements of 21 C.F.R. § 801.109, which include "information for use, including indications, effects, routes, methods, and frequency and duration of administrations, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended."[26] The FDA thus requires that adequate warnings be provided to physicians who, in turn, provide such information to patients as may be necessary in the process of securing informed consent.

### B. The Section 510(k) Premarket Notification And Authorization Process Imposes Preemptive Requirements On Medical Devices.

The device at issue in the present case is a Class III prescription medical device cleared for marketing through the section 510(k) process. As explained above, the section 510(k) process permits the marketing of a new medical device

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22/ 21 U.S.C. § 352(f)(2).

23/ 21 U.S.C. § 352(a).

24/ 21 U.S.C. § 321(n).

25/ FD&C Act § 502(f)(1), 21 U.S.C. § 352(f)(1).

26/ 21 C.F.R. § 801.109(c).



that the FDA has determined is substantially equivalent to a predicate device. A section 510(k) submission must contain proposed labeling for the device and must demonstrate that the device is substantially equivalent in intended use and technological characteristics to the predicate device, or that any technological differences from the predicate device do not render the device less safe or effective than the predicate device.[27]

The FDA may request additional information that it deems necessary to make a determination of substantial equivalence.[28] The additional information required by FDA may include clinical data or design information intended to assure the agency of the safety and effectiveness of the device. If the FDA finds the labeling proposed by the applicant inadequate, it may require alternative labeling as a condition for its substantial equivalence determination.[29] Once a device is cleared for marketing pursuant to the section 510(k) process, the FDA retains the power to call for a PMA for the device to impose more stringent requirements.[30]

In 1990, the statutory language governing the section 510(k) process was substantially strengthened under the Safe Medical Devices Act of 1990 (SMDA). The SMDA

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27/ FD&C Act § 510(k), 21 U.S.C. § 360(k); 21 C.F.R. § 807.87.

28/ 21 C.F.R. § 807.87(k); *see also* Memorandum from David L. West (Deputy Director, Office of Device Evaluation (ODE)) to ODE Review Staff regarding 510(k) Additional Information Procedures (510(k) Memorandum #K93-1) (July 23, 1993) (hereinafter Additional Information Procedures). To illustrate this point, reprinted in Appendix A are some publicly available letters the FDA has sent to medical device manufacturers requesting additional information necessary for the review of their 510(k) submissions.

29/ *See, e.g.*, Appendix A.

30/ FD&C Act § 515(b), 21 U.S.C. § 360e(b).

"confirms the manner in which the agency has implemented the premarket notification provision of the 1976 device law and gives the [FDA] substantial additional postmarket surveillance and penalty authorities."[31/] The FD&C Act now expressly mandates that all relevant information on the safety and effectiveness of the device be included in the section 510(k) submission.[32/] In addition, the SMDA provides that the FDA must issue a formal order embodying its finding that the device either has the same technological characteristics as the predicate device, or does not raise different questions of safety and effectiveness than the predicate device.[33/]

**1. A determination of substantial equivalence involves an evaluation of the safety and effectiveness of the device.**

The FDA's practice of evaluating safety and effectiveness information in making substantial equivalence determinations did not originate with the SMDA. The section 510(k) process historically has involved a review of device safety and effectiveness. In the preamble to the final rule implementing provisions of the SMDA, the agency rejected the notion that an evaluation of safety and effectiveness is outside of the scope of a substantial equivalence inquiry, and it emphasized that the evaluation of a device's safety and effectiveness has always been integral to the substantial equivalence determination.[34/] The agency explained:

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31/ Advisory Committee on the FDA, Final Report, *Report of the Subcommittee on Devices, Radiological Health and Biomedical Research*, App. C, at 16 (May 1991) (hereinafter *Advisory Committee Report*).

32/ FD&C Act § 513(i), 21 U.S.C. § 360c(i).

33/ FD&C Act § 513(i)(1)(A), 21 U.S.C. § 360c(i)(1)(A).

34/ 59 Fed. Reg. 64287, 64288 (Dec. 14, 1994); *see also* H.R. Rep. No. 808, 101st Cong., 2d Sess. 25 (1990); *Advisory Committee Report, supra*, at 16.



> FDA believes that Congress clearly intended the concept of "substantial equivalence" to include some inquiry into the safety and effectiveness of a new device, and that such inquiries into safety and effectiveness are often inseparable from other bases of determining substantial equivalence.[35/]

The position articulated by the FDA in its final rule is supported by the legislative history. Referencing the provisions of the SMDA authorizing FDA to request clinical data in support of section 510(k) applications, the House Committee on Energy and Commerce stated:

> The reference to clinical data is to be read together with the requirement that devices found substantially equivalent may be used with the same assurance of *safety and effectiveness* as similar devices on the market. The Committee believes that such a finding may well necessitate submission of some *clinical data* and intends this provision to *clarify the statutory basis for requiring such information. Again, the Committee does not intend to change current FDA practice regarding this process.*[36/]

The 1986 FDA guidance document for conducting section 510(k) reviews illustrates the FDA's longstanding practice of requesting performance data to substantiate the safety and effectiveness of medical devices. The guidance document stated:

> The Center [for Devices and Radiological Health] normally will require performance testing data to

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35/ 59 Fed. Reg. at 64288.

36/ H.R. Rep. No. 808, at 25 (emphasis added); *see also* H.R. Rep. No. 853, 94th Cong., 2d Sess. 36 (1976) (indicating that safety and effectiveness is a part of the substantial equivalence determination).

> substantiate equivalence if a new device has an important descriptive difference in comparison to marketed devices within its type, and it is *not* clear from an initial review that the device has an intended use or technological change that makes it [not substantially equivalent]; or, the new device has descriptive characteristics that are too imprecise to guarantee that comparability in performance will be achieved even if the new device is produced as described.[37/]

The guidance document used a pacemaker lead, the type of medical device at issue in the present case, to illustrate the circumstances under which performance data would be required.[38/]

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[37/] FDA, Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program, at 12 (June 30, 1986) (hereinafter 1986 Guidance). This guidance did not initiate the practice of requiring supporting performance data. Rather, the guidance document "describes practices that have been developed over many years of program operations." Memorandum from Kshitij Mohan (Director, ODE) to ODE Review Staff regarding Premarket Notification Review Program (510(k) Memorandum #86-3) (June 30, 1986).

[38/] The guidance stated:

> The fact that a new pacemaker lead and a marketed pacemaker lead are both in the polyurethane "family" does not ensure that both devices have the same chemical formulations, and *differences in the chemical formulations of polyurethanes could affect safety or effectiveness. Differences in design, extrusion, and assembly of polyurethanes with the same chemical formulation could also affect safety or effectiveness.* Thus, the Center would generally *require performance testing information* to confirm that the new lead is [substantially equivalent] to the predicate lead.

1986 Guidance, *supra*, at 12 (emphasis added).



A 1993 draft guidance document confirms that the FDA's review of safety and effectiveness data is not limited to devices that differ technologically from predicate devices. This draft guidance applies to agency review of section 510(k) submissions for devices "that do not feature new technological characteristics that raise new types of safety and effectiveness issues."[39/] It delineates certain "basic information" that should be included in a section 510(k) submission, because "[t]his information is necessary in the evaluation of the safety and efficacy, and the substantial equivalence of a device."[40/] Among other things, this basic information includes comparative performance evaluations and, if appropriate, clinical performance evaluations and data.[41/] In addition, the section 510(k) submission should identify and demonstrate compliance to applicable voluntary standards, which may impose additional safety and efficacy requirements on the device.[42/]

The FDA has issued several other guidance documents to assist in the preparation and review of section 510(k) submissions. These documents provide supplemental guidance to FDA reviewers and medical device manufacturers regarding the substantive requirements of section 510(k) submissions. The FDA guidance documents broadly applicable to section 510(k) submissions are updated periodically.[43/] In addition

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[39/] FDA, Reviewer Guidance for Premarket Notification Submissions, at 1 (Draft Nov. 1993) (hereinafter 1993 Guidance).

[40/] *Id.* at 3.

[41/] *Id.* at 2-6.

[42/] *Id.* at 7.

[43/] The most recent FDA guidance on preparing 510(k) submissions is dated March 1995. *See* Addendum: How to Submit a Premarket Notification [510(k)], *reprinted in* International Medical Device Regulatory Monitor, App. A (Mar. 1995).

to the general section 510(k) guidance documents, the FDA has issued a number of guidances applicable to specific types of devices.[44/] These guidance documents, issued both before and after enactment of the SMDA, are tailored to the particular devices in question, and illustrate the importance of safety and effectiveness data in section 510(k) submissions.

**2. The level of scrutiny the FDA imposes on a medical device through the section 510(k) process is based on a reasoned determination of the level of risk posed by the particular device.**

The regulation of medical devices is premised on the FDA's expert authority to determine the appropriate level of regulatory review required to assure the safety and effectiveness of particular medical devices. In implementing the section 510(k) premarket notification and authorization process, the FDA exercises its discretion and expertise to determine the appropriate level of safety and effectiveness information required in a section 510(k) submission and the

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[44/] The FDA has issued guidance documents governing 510(k) submissions for numerous devices, including blood oxygenators (Draft Mar. 1983), magnetic resonance diagnostic devices (Aug. 2, 1988), implantable pacemaker leads (Draft Sept. 1989), picture archiving and communications systems (Feb. 1991), computer controlled medical devices (Aug. 29, 1991), sterilizers intended for use in health care facilities (Mar. 1993), general purpose disinfectants (Oct. 1993), general surgical electrosurgical devices (Draft Oct. 19, 1993), daily wear contact lenses (Nov. 1993), *in vitro* devices (Draft 1994), arthroscopes and accessories (Draft May 1994), medical lasers (Draft Aug. 1994), biofeedback devices (Draft Aug. 1994), sharps safety devices (Mar. 1995), and 2-D laparoscopes (undated).



degree of FDA scrutiny that should be applied in evaluating this information.[45/]

Under its PMA/510(k) Triage Review Procedures, the FDA assigns submissions to one of three tiers, based upon the "inherent risk" of the device.[46/] Tier III is comprised of "all first and second of a kind devices utilizing new technology or having new intended use(s), as well as other PMAs and 510(k)s determined by their inherent risk to require an intensive review." Submissions for Tier III devices are subject to "[i]ntensive scientific and labeling review, using a team review approach." Tier II devices are deemed to pose less of an inherent risk. Section 510(k) and PMA submissions for Tier II devices are subject to "[r]outine scientific and labeling review." Tier I devices pose the lowest inherent risk. Accordingly, submissions for Tier I devices are subject to less scrutiny, consisting of "[e]ssentially a focused labeling review for intended use/indications for use." As the FDA has indicated, however, a review of the label indications and

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[45/] Thus, although certain substantial equivalence determinations for simple devices may require limited descriptive information regarding safety and effectiveness, "when the determination of substantial equivalence is based on an assessment of performance data, the supporting information is generally more voluminous and more complex." 57 Fed. Reg. 18062, 18063 (Apr. 28, 1992).

[46/] Memorandum from Susan Alpert (Acting Director, ODE) to ODE Review Staff regarding PMA/510(k) Triage Review Procedures (General Program #G94-1), at 2 (May 20, 1994) (hereinafter Triage Review Procedures). The Triage Review Procedures provide the flexibility to reassign device submissions among the tiers if information regarding the risk posed by a particular device merits such reassignment. *Id.* All quotations in this paragraph are from this document.

intended use of a medical device still constitutes an assessment of safety and effectiveness.[47/]

The level of safety and effectiveness review required by medical device manufacturers submitting section 510(k) applications also varies depending on the degree of risk posed by the device. Device manufacturers claiming substantial equivalence to a Class III device must conduct a more expansive review of safety and effectiveness data than must manufacturers of Class I or Class II devices.[48/] Under 21 C.F.R. § 807.87(i), such manufacturers must submit:

> a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in § 807.94.[49/]

In the preamble to the interim rule establishing this requirement, the FDA explained why the search of adverse safety and effectiveness information must include all similar marketed devices:

> Limiting the class III summary and class III certification to adverse safety and effectiveness information known

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[47/] *See, e.g.*, 1986 Guidance, *supra*, at 5-6 ("For the purposes of determining whether or not the new device has the same intended use as a predicate device, the Center assesses any differences in label indications in terms of the safety and effectiveness questions they may raise.").

[48/] *See* FD&C Act § 513(f)(3), 21 U.S.C. § 360c(f)(3).

[49/] 21 C.F.R. § 807.87(i)(2); *see also* FD&C Act § 513(f)(3), 21 U.S.C. § 360c(f)(3).



> only about the device for which the premarket notification was submitted and a single predicate or legally marketed device is not consistent with *Congressional intent of ensuring that potential adverse safety and effectiveness concerns of that type of device are adequately addressed in a premarket notification.* This concern particularly applies in situations where there is limited clinical experience with the subject device.[50/]

### C. The Labeling, Manufacture, And Design Of Medical Devices Are Regulated By The FDA Through The Section 510(k) Process And GMP Regulations.

#### 1. Labeling

The FDA imposes labeling requirements for medical devices through the section 510(k) process. Because device labeling is essential to ensuring the safe and effective use of medical devices, section 510(k) submissions must include all labeling (*i.e.*, device labels, instructions for use, promotional material) for the device under review.[51/] If the FDA finds the submitted labeling inadequate or unsupported by information provided in the submission, the agency can request additional information to substantiate the proposed label claims or require the applicant to modify the labeling.[52/] The FDA may suggest alternative language, and often conditions a determination of substantial equivalence on the applicant's ability to resolve the safety or effectiveness issues raised by the agency.[53/]

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[50/] 57 Fed. Reg. at 18064 (emphasis added).

[51/] 21 C.F.R. § 807.87(e); 1993 Guidance, *supra*, at 7.

[52/] *See, e.g.*, Appendix A.

[53/] *Id.*

## 2. Design and manufacture

Device design is essential to a determination of substantial equivalence. An evaluation of the technological characteristics of the medical device, including device design, historically has been the cornerstone of safety and effectiveness evaluations in the section 510(k) process. For example, the 1986 FDA guidance on the premarket notification review program explained that technological differences must be evaluated as a part of the substantial equivalence determination and that the section 510(k) submission must "explain why the device does not present new questions about safety or effectiveness, describe what accepted methods exist to test comparability of performance, and present data, generated from such tests, that demonstrate comparability."[54/]

As FDA explained in its interim rule to implement the provisions of the SMDA:

> FDA generally will require performance testing data to establish substantial equivalence if a new device has *different technological characteristics* than a predicate or legally marketed device, or when the descriptive characteristics of the devices are insufficient to ensure that the devices will perform comparably. In these cases, *performance testing data are necessary to demonstrate that the new characteristics of the device do not cause it to perform less safely or less effectively* than the legally marketed device to which it is being compared.[55/]

The FDA may also exercise control over the design of a medical device by refusing to grant marketing authority under section 510(k) based on certain identified technological characteristics of the device, which the agency determines

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[54/] 1986 Guidance, *supra*, at 8, 11.

[55/] 57 Fed. Reg. at 18063 (emphasis added).



raise concerns of safety or effectiveness. For example, in reviewing a section 510(k) application for a nerve locator/stimulator, the FDA found that the device was substantially equivalent to a predicate device.[56/] Based on a scientific evaluation of the device, however, the FDA found that certain aspects of the device's design rendered it unsafe. To address the FDA's concerns, the device manufacturer made specific design modifications to the medical device. Notably, this incident occurred in 1978, only two years after the effective date of the MDA and more than a decade before the SMDA was enacted.

As explained above, the FDA's GMP requirements comprehensively regulate the manufacture, release and postmarket surveillance of medical devices. In addition, the GMP regulations operate together with the section 510(k) substantial equivalence determination to impose specific design controls and requirements on medical devices.[57/] The FDA's draft guidance document, "Deciding When to Submit a 510(k) for a Change to an Existing Device," provides guidance to manufacturers in determining when a change to a currently marketed device merits a new section 510(k) submission. The draft guidance explains how the section 510(k) premarket notification and authorization process and the GMP regulations operate together to assure that medical devices are safe and

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[56/] Relevant publicly available correspondence between the FDA and the manufacturer relating to this device is reprinted in Appendix B.

[57/] The FDA has proposed a new GMP regulation that will directly address design controls for new devices. *See* 58 Fed. Reg. 61952 (Nov. 23, 1993) (Proposed Rule); 60 Fed. Reg. 37856 (July 24, 1995) (Notice of Availability and Announcement of Public Meeting). As the FDA has stated, however, the current GMP regulation "is not silent on device design," by virtue of the design change and process validation requirements in the existing rules. FDA, Deciding When to Submit a 510(k) for a Change to an Existing Device 2 (Draft #2 Aug. 1, 1995).

effective in their manufacture *and* design.[58/] The FDA explained that "[a]ny guidance on 510(k)s for changes to a marketed device must consider the role of the Good Manufacturing Practices (GMP) regulation in changes in device design."[59/] Responding to comments submitted regarding an earlier draft of the guidance, the FDA explained the interplay between the section 510(k) process and the GMP regulations in controlling device design:

> In this draft guidance, the reliance on design validation of changes under GMP is much more explicit, and, in many instances, the results of design validation activities are identified as indicators of when a change is significant enough to merit a premarket notification.[60/]

Thus, medical devices marketed through the section 510(k) process are not "frozen" technologically in a pre-1976 state. Rather, appropriate changes in manufacture and design continue to occur both before and after section 510(k) notifications are filed. These changes are all subject to the FDA's oversight to assure the safety and effectiveness of the new devices. Such incremental advances ensure that the quality of medical devices continues to improve over time.

## II. PERMITTING STATE PRODUCT LIABILITY AND RELATED CLAIMS TO PROCEED AGAINST MEDICAL DEVICE MANUFACTURERS WOULD STIFLE INNOVATION AND IMPEDE THE AVAILABILITY OF IMPORTANT MEDICAL TECHNOLOGIES.

In enacting the MDA, Congress recognized that the application of state or local requirements to medical devices

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58/ *Id.*

59/ *Id.*

60/ *Id.* at ii.



would threaten technological innovation in the medical device industry. By placing the safety and effectiveness of medical devices exclusively in the FDA's authority, Congress struck a careful balance so that safety and effectiveness requirements would not hinder research and development of new medical devices.[61/] Congress decided that the FDA alone should regulate the safety and effectiveness of medical devices, without being second-guessed by lay juries in the 50 states.

Congress's concern is not unfounded. A 1988 report of the American Medical Association (AMA) Board of Trustees concluded that "[p]roduct liability is having a profound negative impact on the development of new medical technologies."[62/] The report explained:

> Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance. Certain older technologies have been removed from the market, not because of sound scientific evidence indicating lack of safety or efficacy, but because product liability suits have exposed manufacturers to unacceptable financial risks.[63/]

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61/ *See* H.R. Rep. No. 853, at 12 (1976) (Congress enacted the MDA to protect public health and to ensure "innovations in medical device technology are not stifled by unnecessary restrictions"); S. Rep. No. 33, 94th Cong., 1st Sess. 2 (1975) (the MDA was intended both to encourage the research and development of "sophisticated, critically important medical devices" and to give the FDA the authority necessary to ensure public health and safety).

62/ AMA, *Report of the Board of Trustees: Impact of Product Liability on the Development of New Medical Technologies* 1 (June 1988) (hereinafter *AMA Report*).

63/ *Id.*

### A. The Imposition Of Awards Against Medical Device Manufacturers Under State Law Would Impede The Development Of Important Medical Technologies.

A 1993 Institute for Civil Justice (ICJ) report noted: "Innovation is of social concern because of its potential to enhance future product safety and effectiveness and to reduce health care costs."[64] The ICJ report emphasized that "[e]ffects on innovative effort may be the most important element of the effects of liability on the economic performance of these industries."[65] Another report echoed this sentiment: "The result of this liability expansion has been a slowing of innovation in entire fields of inquiry, especially those having to do with health care."[66]

The ICJ report explained that while "[t]he economics of the industry impel companies to innovate, . . . liability concerns may steer them away from some types of innovation that appear to pose relatively large liability threats."[67] Unfortunately, the product areas with the largest potential

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[64] Steven Garber, *Product Liability and the Ec nomics of Pharmaceuticals and Medical Devices* 142 (1993). This report is based on a study conducted by Steven Garber, supported by the Institute for Civil Justice. RAND, the publisher of the report, is a nonprofit institution that seeks to improve public policy through research and analysis.

[65] *Id.*

[66] Richard J. Mahoney & Steven E. Littlejohn, *Innovation on Trial: Punitive Damages Versus New Products*, Science, Dec. 15, 1989, at 1395, 1397; *see also* Peter W. Huber, *Liability* 160 (1988) ("Whatever intuition may tell us, newer is generally safer than older in the modern technological world. Slowing the pace of innovation did not advance safety in the least; it set it back sharply.").

[67] Garber, *supra*, at 144.



liability are often those with the greatest potential public health benefits, such as life-saving technologies.

### B. The Imposition Of State Awards Would Threaten The Availability Of Critical Medical Technologies.

Product liability awards can have a significant impact on the availability of valuable medical technologies. As the ICJ report noted, the possibility of large liability and defense costs "can create enormous uncertainty for companies no matter how responsible their behavior."[68]

#### 1. Useful products have been withdrawn because of liability concerns.

Biomaterials are natural or synthetic materials that are used in medical devices that will be in contact with body fluids, tissues, or both. Biomaterials are essential to a variety of life-saving and life-quality-enhancing medical devices. Because of product liability exposure, however, companies have been discouraged from pursuing the research, development and supply of biomaterials.[69] Research in the biomaterials field has "contributed to lifesaving technological advances, such as treatments for defective heart valves, hydrocephalus, failing heart rhythms, detached retinas, and other medical problems."[70] Determining that the liability

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[68] *Id.* at 91 (footnote omitted).

[69] *FDA Regulation of Medical Devices, Including the Status of Breast Implants, Joint Hearing Before the Subcomm. on Human Resources and Intergovernmental Relations and the Subcomm. on National Economic Growth, Natural Resources, and Regulatory Affairs of the House Comm. on Government Reform and Oversight*, 104th Cong., 1st Sess. 181-182 (Aug. 1, 1995) (statement of James S. Benson, Senior Vice President for Technology and Regulatory Affairs, HIMA) (hereinafter Benson Statement).

[70] James S. Benson, *Biomaterials*, Med. Device & Diagnostic Indus., April 1995, at 34.

exposure is too great, many biomaterials suppliers either have withdrawn particular biomaterials from the medical device market or have left the device market altogether.[71] As a result, manufacturers of critical medical devices are having difficulty obtaining the raw materials vital to their products.[72]

The biomaterials shortage could have a devastating impact on patient care, restricting the availability of medical devices over "the entire spectrum of medical specialties, from cardiology and neurology to urology and ophthalmology."[73] The medical devices thus imperiled include heart valves, vascular grafts, pledgets (surgical tools), and intraocular lenses.

Products liability exposure for biomaterials manufacturers has particularly threatened the availability of life-saving hydrocephalus shunts.[74] Among other things, hydrocephalus shunts are used for draining the build-up of cerebrospinal fluid from the brains of affected infants or adults.[75] Approximately 75,000 of these shunts are implanted annually.[76]

An essential component of hydrocephalus shunts, silicone, has been particularly targeted by product liability claims.[77] Numerous other products rely on the availability of silicone, including arthroplasty devices (artificial joints), catheters,

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[71] Benson Statement, *supra*, at 181.

[72] *Id.*

[73] *Id.* at 182.

[74] *Id.*

[75] *Id.*

[76] *Id.*

[77] *See* Gregory M. Lee, *The Use of Silicone as a Biomaterial*, Med. Device Technology, April 1995, at 20.



intravenous drip systems, cardiac pacemaker leads, implantable infusion pumps, wound drainage sets, ostomy systems, and several different types of grafts. Potentially enormous liability exposure has driven some silicone manufacturers out of the market, placing the availability of these critical medical devices at particular risk.[78]

Polyester (PET) yarn provides another example of a biomaterial whose availability is threatened by product liability exposure.[79] PET yarn has been used for permanent implants since the 1950's, and "is considered a highly reliable, safe material used as a standard building block by permanent implant manufacturers."[80] Because of product liability exposure, however, both domestic and foreign manufacturers have been discouraged from supplying PET yarn for use in the permanent device implant market.[81]

Product liability awards, or the threat of such awards, have impeded the availability of other medical devices as well. According to one source, product liability exposure caused the "sole domestic manufacturer of anesthesia gas machines" to stop producing these devices in 1984, "leaving the market to two foreign competitors."[82] Also influenced by liability concerns, one company "has foregone developing a suitcase-sized kidney dialysis unit and offering intravenous equip-

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[78] *Id.*

[79] *See* Aronoff Associates, Market Study: Biomaterials Supply for Permanent Medical Implants (March 1994). The Aronoff study was commissioned by HIMA to examine three materials, including PET yarn.

[80] *Id.* at 9.

[81] *Id.* at 14.

[82] Mahoney & Littlejohn, *supra*, at 1397.

ment."[83] Product liability exposure also may threaten the availability of infant sleep apnea monitors.[84]

**2. Liability awards would impose social costs, with no countervailing public benefits.**

Referencing the "profound negative impact" that product liability issues have on the "development and utilization of potentially life-saving medical technologies," the AMA stated: "Laws developed to protect the public at large can sometimes hurt the very individuals they were meant to protect."[85] This is certainly true where state product liability awards are imposed on manufacturers of FDA-regulated medical devices. "Capable of managing the uncertainties of research but not the uncertainties of law, companies have no choice but to avoid the courtroom by withdrawing products, keeping others off the market, and restricting the scope of research and development at its earliest stages."[86] The imposition of product liability produces no apparent public benefit to counterbalance its detrimental effects:

> Arguments that the proliferation of liability suits are somehow related to an increase in unsafe products are also not supported by facts, as no relation can be found between the two. Priest concludes that "data on deaths and injuries cast great doubt on the proposition that the liability crisis derives from an increase in the underlying accident rate" and "provide no evidence that the

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[83] *Id.*

[84] Kevin M. Quinley, *Avoidance: Dodging the Liability Bullet,* Med. Device & Diagnostic Indus., June 1991, at 44. Mr. Quinley is the Senior Vice President for Risk Services at Hamilton Resource Corp. and MEDMARC.

[85] *AMA Report, supra*, at 12.

[86] Mahoney & Littlejohn, *supra*, at 1395.



> expansion of litigation has affected the injury or death rate."[87]

The imposition of product liability awards on medical device manufacturers under state law may carry other, less apparent, social costs as well. For example, such actions might impair the practice of medicine by inappropriately influencing a physician's prescribing decisions.[88]

Thus, product liability awards deter important research and development activities in the medical device field and impede the availability of valuable medical technologies in a myriad of ways. Recognizing the serious detrimental effects that product liability exposure would have on the advancement of medical device technology, Congress wisely placed regulation of the safety and effectiveness of medical devices solely within the FDA's expert authority.

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[87] *Id.* at 1396 (citations omitted).

[88] Garber, *supra*, at 36.

## CONCLUSION

The judgment of the court of appeals should be reversed in part as requested in Medtronic's petition in No. 95-754 and remanded with directions to affirm the judgment of the district court.

Respectfully submitted,

Of Counsel:

DONNELLDA RICE
General Counsel
Health Industry
Manufacturers Association
1200 G Street, N.W.
Washington, D.C. 20005
(202) 783-8700

BRUCE N. KUHLIK
*Counsel of Record*
JENNIFER A. JOHNSON
Covington & Burling
1201 Pennsylvania Ave., N.W.
Washington, D.C. 20044
(202) 662-6000
*Counsel for Health Industry Manufacturers Association*

PAUL J. MALONEY
WILLIAM J. CARTER
SAMUEL J. SMITH, JR.
Carr, Goodson, Lee & Warner
1301 K Street, N.W.
East Tower - Suite 400
Washington, D.C. 20005-3300
(202) 310-5500
*Counsel for MEDMARC Insurance Company, Inc.*

March 13, 1996

# APPENDICES

APPENDICES

**APPENDIX A**

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

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Public Health Service
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

DEC 18 1989

Pekka T. Sipila, M.D.
Noraxon USA Inc.
8381 E. Gelding Drive
Scottsdale, Arizona
85260

Re: K895635
Myosystem 1000
"Electromyograph"
Dated: September 11, 1989
Rec'd: September 19, 1989

Dear Dr. Sipila:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. In order for us to complete the review of your submission, we require the following information:

1. You must provide proof of pre-Amendments commercial marketing of the Myoexorciser 1000 by Verimed, if you intend to use this as the comparison device for demonstrating substantial equivalence. You must provide a point by point comparison of the intended uses of your device to the device to which you are claiming substantial equivalence.

2. You must revise the promotional materials for the Myosystem 1000 to delete the following claims:

a. diagnosing muscular diseases, paralysis, rheumatism and spasms and measuring rehabilitation progress;

b. analyzing a single action cycle of one muscle and provide wave form analysis, e.g., during maximum weight lifting;

c. monitoring strength, power, speed, endurance, coordination, and reaction time in for sports medicine training;

d. measuring muscle loading and the quality of work conditions, tool designs, and working techniques development in work ergonomics/occupational medicine;

e. analyzing rhythmics to compare temporal values of successive action cycles with each other;

f. analyzing coordination of any two muscles;

g. monitoring success of rehabilitation program; and

h. measuring an athlete's EMG activity throughout performance.

Otherwise, you must include proof of pre-Amendments commercial marketing of EMG biofeedback devices for these intended uses and valid scientific data substantiating these claims.

3. You must label the Myosystem 1000 as a prescription device.



4. If you submit additional information that sufficiently addresses the above concerns, then you will need to submit a point by point comparison of the technological characteristics of the Myosystem 1000 and the device to which you are claiming substantial equivalence. This must include, but should not be limited to:

   a. sensitivity range(s) and accuracy;

   b. low noise amplifier:

      i. input noise;

      ii. differential Input Impedance;

      iii. input current;

      iv. common mode rejection ratio;

   c. notch filter;

   d. filter bandpass and rejection levels; and

   e. accuracy of each type of EMG display accuracy.

5. You must clarify each of the main functions that are performed and how they are performed, e.g., endurance analysis, rhythmics analysis, coordination analysis, etc.; enlarging sample diagrams/waveforms and more complete labeling of these enlargements might be useful. All columns must be identified on the analyses printout, e.g., sample rhythmics analysis. Definitions of all terminology (e.g., maxima, minima, etc.) and explanations of the results from the must be included. The names of these functions must be revised to be consistent with the labeling changes noted in #2

above. This information and revisions must be included in the user's manual.

6. You must explain why the endurance analysis requires a submaximal performance of a single muscle and how the clinician is to account for the variation in the amount of contraction provided with each successive repetition.

7. You must clarify whether or not the EMG signal (raw or integrated) is superimposed onto a grid; if not, how can the clinician check the accuracy of the coordinates?

8. You must explain why you are recommending that the integrated curves be smoothed and explain how this affects the accuracy and overall analysis.

9. You must delete claims that the signal is free of distortion within the EMG frequency domain and that the Myosystem 1000 only picks up the actual EMG activity and does not distort this signal in the process.

10. You must substantiate the claim that EMG signals as weak as 0.01 microvolt pose no problem for the instrument.

11. You must provide additional information regarding the software as follows:

    a. You must provide a description of how each main function is performed, i.e., clarify how the results are generated.

    b. Provide a brief narrative which explains the methods and procedures used for software validation and verification throughout the software



development lifecycle and software maintenance once the device is in commercial distribution.

    c. Explain the safety measures incorporated within the system to protect the user/patient in the event of a software failure.

    d. Describe the recommended user practices for monitoring system performance.

    e. Can the user change the software of the device and, if so, are there any limitations/controls on these changes? Is the software protected from inadvertent changes/deliberate tampering?

12. You must clarify whether the device design conforms to any voluntary standards, e.g., UL-544, and specify how it conforms. Specify how the device is isolated from each accessory device with which it interfaces, and whether the channels are isolated from each other.

13. Provide a point by point comparison of the technological characteristics for each accessory (included in this premarket notification submission) and for a comparison device, including but not limited to:

    a. materials and construction of each accessory, e.g., electrode cables, electrode adapters, system cable, surface and needle electrodes, electroconductive medium, printer, etc.

    b. electrical specifications of each powered accessory, including but not limited to power source, current leakage values, line isolation methods, etc.; and

c. clarification as to whether the device design conforms to any voluntary standards, e.g., UL-544.

d. information on the method of sterilization, the level of sterilization, the method of testing to assure compliance with this method and level of sterilization, and an explanation of why the method used does not damage the materials used in the construction of the needle electrodes, if needle electrodes are provided;

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a pre-Amendments device with regard to its safety and effectiveness.

You may not market this device until 90 days after you have provided adequate information described above and required by 21 CFR 807.87(f) and (h). If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act).

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be re-submitted so that your new 510(k) is complete.



If you have any questions concerning the contents of this letter, please contact J. Blackwell, D.V.M., M.P.H., at (301) 427-1036.

Sincerely yours,

s/
Carl A. Larson, Ph.D.
Director, Division of Surgical
and Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

January 23, 1985

E. Aubrey Woodroof, Ph.D.
President
Woodroof Laboratories
3100-7 Harvard Street
Santa Ana, California
92704

Re: K844052
BIOBRANE™ Brand
Temporary Wound
Dressing
with Adhesive Strip
Dated: September 28, 1984
Received: October 18, 1984

Dear Dr. Woodruff:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to one marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled for use on third degree burns or for use on full thickness skin wounds of any nature without specific Food and Drug Administration (FDA) approval for such labeling.



2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization without evidence of said effect being reviewed and approved by the FDA.

3. This device may not be labeled as a long-term or permanent, no change dressing, or as an artificial or synthetic skin without specific FDA approval for such labeling.

4. This device may not be labeled for use on vascular stasis ulcers without specific FDA approval for such labeling.

The labeling submitted does not comply with the above limitations. We suggest that you make the necessary changes in the labeling, and that before marketing the device in this country, you submit the revised labeling for review to the Division of Compliance Operations (HFZ-320) at the address noted below. If you are notified that the revised labeling is satisfactory, you may begin marketing your device subject to the general controls imposed by the Act.

You may market your device until such time as your device has been classified under Section 513. At that time, if your device is classified into either Class II (Standards) or Class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the future, the scope of general controls may be broadened to include additional regulations.

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the FDA will be published in the FEDERAL REGISTER. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

s/
Robert G. Britain
Director
Office of Device Evaluation
Center for Devices and
Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

NOV 6, 1989

Mr. Juergen F. Kopf
Vice President
Nemectron
28069 Diaz Road
Unit A
Temecula, California
92390

Re: K895000
Nemectron Microwave
Dated: July 28, 1989
Received: August 8, 1989

Dear Mr. Kopf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. In order for us to complete the review of your submission, we require the following additional information and changes to the labeling:

1. Your brochure shows application over the pelvis. Shortwave diathermy should not be applied to the gonads and therefore, this application must be deleted both explicitly or implicitly in any material relating to this device. A statement must be added to the contraindications section of your labeling which states, "Shortwave diathermy should not be applied to the gonads or to the developing fetus."

2. The following contraindications must be added to the operating manual:

(a) treatment of patients wearing IUD's containing copper or other metals;

(b) treatment of unconscious patients; and

(c) for local healing of ischemic tissues.

3. The statement "Any type of high frequency treatment of neoplasms should be supervised. . ." must be deleted. Neoplasms should not be treated by shortwave diathermy.

NOTE: ALL LABELING MUST COMPLY WITH DRAFT GUIDANCE DOCUMENT "PROPOSED GUIDELINES FOR LABELING OF SHORTWAVE DIATHERMY DEVICES FOR THERAPEUTIC PURPOSES" (copy enclosed).

4. State the peak and average power for all settings for each output mode.

5. Do all device settings produce 40-45°C heat in deep tissues?

6. Are the generator and cables impedance matched to the applicators?

7. Does the device meet stray radiation standards? How is the stray radiation measured and what are the values reported?

We believe that this information is necessary for us to determine whether or not this device is substantially



equivalent to a pre-Amendments device with regard to its safety and effectiveness.

You may not market this device until 90 days after you have provided adequate information described above and required by 21 CFR 807.87(f) and (h). If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act).

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be re-submitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Michael J. Blackwell, D.V.M., M.P.H., at (301) 427-1036.

Sincerely yours,

s/
Carl A. Larson, Ph.D.
Director, Division of Surgical
and Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

JUL 31 1986

Mr. Magnus Ahlen
President
Suntec Health & Fitness
Group, Inc.
P.O. Box 2668
Westport, Connecticut 06880

Re: K862293
Electro Trim
Dated: April 1, 1986
Received: June 17, 1986
Regulatory Class: II

Dear Mr. Ahlen:

Your Section 510(k) notification of intent to market the above-referenced device has been reviewed. We have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments.

However, we would regard the Electro Trim to be misbranded under the provisions of the Federal Food, Drug, and Cosmetic Act (Act) due to its misleading name, and the labeling you submitted. Muscle stimulators, regardless of design, are considered to be prescription devices subject to labeling requirements of 21 CFR 801.109 (copy enclosed). Only the following intended uses are considered acceptable:

1. relaxation of muscle spasm;



2. prevention or retardation of disuse atrophy;

3. increasing local blood circulation;

4. muscle re-education;

5. immediate postsurgical stimulation of calf muscles to prevent venous thrombosis; and

6. maintaining or increasing range of motion.

We suggest that you make the necessary changes to the trade name and labeling before marketing this device and you submit such notification for review to the Division of Compliance Operations (HFZ-320). If you are notified that the revised labeling is satisfactory, you may begin marketing your device subject to the general controls provisions of the Act. This device has been placed into the regulatory class shown above, by a final regulation published in the Federal Register. All classes of devices are regulated by the general controls provisions of the Act applicable to all medical devices including annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act; class II devices must also meet present or future performance standards; class III devices will be required to undergo premarket approval at some time in the future.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. We suggest you subscribe to this publication so you can convey your views to the FDA if you desire and be notified of any additional requirements subsequently imposed on your device.

Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

s/
David L. West, Ph.D.
Associate Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

bcc:HFZ-401 DMC
HFZ-403 RChissler
HFZ-410 DSRD
f/t:HFZ-410/SLPhillips/bls/7/2/86
corr:bls/7/11/86



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

DEC 28, 1989

Mr. Lee Cole
President
American Hair Removal System
160 South May Street
Southern Pines, North Carolina
28387

Re: K892514
AHRS Epilator 629
Dated: September 28, 1989
Received: October 6, 1989

Dear Mr. Cole:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following additional information:

1. data to support your hair bulb pH measurements, including a description of the method, and a comparison to pH for plucked and conventionally epilated hairs, and references;

2. data to support the claim that your device delivers electrical current to the dermal papilla equivalent to that delivered by a marketed epilation device, including a description of and justification for the method used;

3. a comparison of the force, in pounds, required to remove hairs treated with your device and a marketed epilation device, including a description of the method used;

4. data from a clinical investigation, preferably according to Section IV of "Official Standards for the Treatment of Permanent Hair Removal" of the International Guild of Professional Electrologists, directly comparing the use of your device to a marketed epilation device; and

5. a full report of histological examination of the roots of hairs epilated with your device.

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a pre-Amendments device with regard to its safety and effectiveness.

You may not market this device until 90 days after you have provided adequate information described above and required by 21 CFR 807.87(f) and (h). If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.



If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be re-submitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Mr. Roger W. Barnes at (301) 427-1090. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely, yours,

s/
Carl A. Larson, Ph.D.
Director, Division of Surgical
and Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

JAN -9 1987

Mr. J. N. Upton
Rapidex
16 Jacobs Well Mews
George Street
London W1H 6BD, England

Re: K862282A
Rapidex Biological Surfactant
Dated: October 23, 1986
Received: October 30, 1986

Dear Mr. Upton:

This is in response to your 510(k) premarket notification submission for the above referenced device. In order to complete our review of your submission, we need the following additional information:

1. A draft copy of all labeling that will be used in the United States. The claims for the product must reflect what the user would expect from Rapidex when following the instructions for use. The present instructions for use are for a concentration of 1.75 ounces of Rapidex per 1.5 gallons of water at room temperature for a 5 minute contact time and, implied, under sterile conditions. If the claims are based on other use conditions, such as saline instead of water, higher temperatures, and/or different concentrations of Rapidex, these conditions must also be listed in the labeling. For



example, if specific use conditions are required to kill certain microorganisms, these conditions must be identified in the labeling for each specific or group of organisms.

Based on the information and the data that you have previously submitted, Rapidex can be considered as a surfactant with bacteriostatic activity. The data indicate that Rapidex may have some limited bactericidal action against gram negative organisms and little action against some gram positive organisms. Data from the single test on HTLV III/LAV/HIV viruses are not enough to support a general viricidal claim for Rapidex. The data do not support claims that Rapidex is fungicidal.

2. A copy of the "User Leaflet" which contains full instructions for the use of Rapidex for the customers in the United States.

3. A copy of the draft label that is planned to be used on the sachet sold in the United States.

4. Detailed information on the laboratory method used to test the viricidal action of Rapidex on HTLV III/LAV/HIV viruses. Also detailed results of the viricidal testing that was performed on the viruses.

5. The name and description of the a product similar to Rapidex to which you claim substantial equivalence, that was sold in the United States prior to May 28, 1976.

The additional information should be submitted, in duplicate, referencing the 510(k) number above, to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have any questions concerning your 510(k) submission, please contact Mr. George Mills, General Hospital and Personal Use Devices Branch, at the above address or at (301) 427-7750.

Sincerely yours,

s/
Fernando Villarroel, Ph.D.
Director
Division of Gastroenterology-Urology
and General Use Devices (HFZ-420)
Office of Device Evaluation
Center for Devices and
Radiological Health

**APPENDIX B**

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MD 20910

DEC 7 1978

Mr. J. R. Moore
Manager
Corporate Regulatory Affairs
Intermedics, Inc.
Box 617
240 Tarpon Inn Village
Freeport, TX 77541

Ref: K781569A - Nerve Locator/Stimulator

Dear Mr. Moore:

Your Section 510(k) notification of intent to market a direct current nerve locator/stimulator has been reviewed. We have determined the device to be substantially equivalent to another direct current nerve locator/stimulator marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976.

However, our scientific staff informs me that the application of direct current to an exposed nerve by means of this device may injure the nerve thereby causing a paralysis. Based on an electrode of 0.03 inch diameter with a minimum output current of 0.5 milliamperes a charge density of 500 microcoulombs per $cm^2$ will be reached within 5 milliseconds. A charge density of 500 microcoulombs per $cm^2$ has been demonstrated to cause an alkaline pH shift and hydrogen gas production at the stimulating electrode which can result in lesion of the nerve

tissue. To date we have seen no documentation which contradicts this finding.

Because it is not possible to accurately regulate by manual control, the period of time a patient is exposed to this device, we believe that your device may be unsafe for its intended purpose.

In view of this, we would appreciate receiving from you any data which demonstrates that your device is safe for its intended use, or that our opinion in this matter is incorrect. You should be aware that if we determine your device is unsafe, and the device has been marketed, your device may be subject to the appropriate sanctions offered by the Federal Food, Drug, and Cosmetic Act.

Please contact Dean A. Barlow, Division of Compliance Operations, Bureau of Medical Devices, 8757 Georgia Avenue, Silver Spring, Maryland 20910 with your reply to this letter as soon as possible.

Sincerely yours,

s/
David M. Link, Director
Bureau of Medical Devices



SURGITRONICS
Tarpon Inn Village • P.O. Box 616
Freeport, Texas 77541 • (713) 233-0201

December 28, 1978

Mr. Dean A. Barlow
Division of Compliance Operations
Bureau of Medical Devices
8757 Georgia Avenue
Silver Springs, Maryland 20910

Dear Mr. Barlow:

This letter is in reply to your request for information on the safety of our disposable nerve locator/stimulator. In a spirit of cooperation and good faith, we stopped production of these devices shortly after receipt of your letter.

We have reviewed the scientific articles that Mr. J. R. Veal provided as references. Appendix A summarizes our arguments regarding the safety of the existing nerve locators.

We have decided to add a series capacitive coupling network to the existing circuitry which limits the period of time that the nerve locator delivers stimulation current to body tissue. The decision to add the coupling network was made because the operation of the device will be improved since the potential of damage to nervous tissue by misuse of the product by physicians has been reduced; and also because a long and expensive debate with your agency on this subject would not benefit anyone. Appendix B lists the

circuitry and performance graphs of the nerve locator with capacitive coupling.

After your scientific staff has reviewed our data in Appendix B, please contact me as soon as possible regarding their opinions and the necessity to file additional or supplemental 510(K) reports with your agency.

Sincerely yours,

s/
Steven A. Barton
President

SAB:bw

Enclosures

cc: Mr. Alfred B. Beers
Executive Vice President
Intermedics, Inc.



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MD 20910

January 24, 1979

Mr. Steven A. Barton, President
Surgitronics
Tarpon Inn Village
P.O. Box 616
Freeport, Texas 77541

Ref: K781569

Dear Mr. Barton:

This is in response to your letter of December 28, 1978, and follow-up telephone calls regarding the Nerve Locator and Stimulator.

Your submission dated December 26, 1978, Appendix A-B of the Intermedics Disposable Nerve Locator Models 554-01/2 has been reviewed and we offer the following comments.

In our December 7, 1978, letter regarding the status of the devices we raised specific objection to the application of direct current in a manner which could cause paralysis. Your modifications as listed in Appendix B would appear to have corrected the objectionable operational characteristics of the original nerve locator. We, therefore, have no objection to the marketing of this modified device.

You are also advised that an additional 510(k) submission for the model 554-02 will not be necessary. You have discussed this with Mr. Veale by phone recently and he concurs that the proposed future modification to the 554-02 would not be significant enough to warrant the submission of another 510(k).

We have been requested to furnish a copy of this letter to Mr. Redner, however, we are electing to limit this correspondence to you. Whether you send a copy to Mr. Redner is your choice.

Should there be any further questions please contact this office directly.

Sincerely yours,

s/
Dean A. Barlow
Division of Compliance Operations
Bureau of Medical Devices

cc:
HOU-SEC (HFR-6300)
ATL-DO (HFR-4100)
HFK-430 (Veale)
HFK-113 (Matthews)
HFK-116 (DAB) (r/f)
HFK-110 (p/c)
HFA-224
Board

DABarlow:mn:1/19/79
Init:BLSchrivener:1/24/79
t/f:lar:1/26/79